Q3 Announcement 2019

ABOUT THIS ANNOUNCEMENT

This Q3 Interim Communication as of 30 September 2019 should be read in conjunction with 4SC's Annual Report for the 2018 financial year, the Q1 Announcement as of 31 March 2019 and the Half-Year Report as of 30 June 2019.

The report at hand contains certain forward-looking statements that are subject to risks and uncertainties that are described, with no claim to be exhaustive, in the section entitled "Report on opportunities and risks" in the Annual Report 2018, and also in the "Opportunities and risks" section of this Q3 Announcement. In many cases, these risks and uncertainties are outside of 4SC's control and may cause actual results to differ materially from those contemplated in these forward-looking statements. 4SC expressly does not assume any obligation for updating or revising forward-looking statements to reflect any changes in expectations or in events, conditions or circumstances on which such statements are based.

ABOUT 4SC

4SC is a clinical-stage biopharmaceutical company developing small-molecule drugs that can target key indications in cancer with high unmet medical needs.

4SC's pipeline is protected by a comprehensive portfolio of patents and currently comprises two drug candidates in clinical development: resminostat and domatinostat.

4SC aims to generate future growth and enhance its enterprise value by entering into partnerships with pharmaceutical and biotech companies and/or the eventual marketing and sales of approved drugs in select territories by 4SC itself.

4SC is headquartered in Planegg-Martinsried near Munich, Germany. The Company had 47 employees as of 30 September 2019 and is listed on the Prime Standard of the Frankfurt Stock Exchange (FSE Prime Standard: VSC; ISIN: DE000A14KL72).

BUSINESS REVIEW IN Q3 2019 / YTD AND OUTLOOK

Key events in Q3 2019 and beyond were each made public via a press release. Details can be found in the relevant releases available at www.4sc.com.

RESMINOSTAT

Resminostat is an orally administered class I, IIb and IV HDAC inhibitor which is well tolerated and can inhibit tumor growth and proliferation and cause tumor regression.

Pivotal RESMAIN study in CTCL

In 2016, 4SC started the pivotal RESMAIN study – a randomized, double-blind, placebo-controlled clinical Phase II study of resminostat in cutaneous T-cell lymphoma (CTCL).

The RESMAIN study is focused on patients with advanced-stage CTCL. Such patients suffer from painful and itchy skin lesions resulting in disfigurement and a severely impaired quality of life. None of the current therapeutic options achieve sustainable clinical benefit, with most patients progressing within six months (on average). Resminostat is being evaluated as a maintenance treatment – prolonging the period patients are stable and not progressing combined with a beneficial decrease of disease-related itching.

The design of the RESMAIN study is based on the advice of external experts and the European Medicines Agency (EMA). The study will likely include more than 180 patients. It is currently being conducted at more than 50 centers across 11 European countries, and at 5 centers in Japan where Yakult Honsha Co., Ltd., 4SC's Japanese development partner for resminostat, is responsible for the conduct of the study.

The Data Safety Monitoring Board, an independent committee of clinical and drug safety experts, evaluated data after 50 and 100 patients have been treated in the study and observed no safety issues. The committee recommended continuation without modification of the study protocol.

To date more than 140 patients have been enrolled in the RESMAIN study and 4SC expects that sufficient patients will be enrolled during 2019 to accumulate the 125 events – i.e. patients experiencing disease progression – around the middle of 2020. Top-line results from the study would be available as soon as possible thereafter.

If the study results are positive, 4SC plans to submit applications for marketing approval of resminostat in CTCL in Europe and potentially the U.S. and Yakult Honsha will submit in Japan. If approved, resminostat would be the first HDAC inhibitor approved for CTCL in Europe and the first and only drug approved for maintenance therapy in this indication in either Europe, Japan or the U.S.

Phase II study in biliary tract cancer

In April 2018, Yakult Honsha initiated a randomized, double-blind, placebo-controlled, multi-center Phase II study evaluating the combination of resminostat and S-1 chemotherapy versus S-1 chemotherapy plus placebo as second-line treatment in 100 Japanese patients with unresectable or recurrent biliary tract cancer. The study is based on a positive Phase I clinical study which was completed in September 2017.

S-1 is a chemotherapy combination drug which is approved for the treatment of several solid tumor types including biliary tract cancer in Asia. The main goal of the study is to prolong progression free survival (PFS) and secondary objectives include efficacy and safety parameters. The study is fully enrolled and final results are expected to be available in the first half of 2020.

DOMATINOSTAT

Domatinostat is an orally administered small molecule class I selective HDAC inhibitor. It has been investigated in a Phase I study in 24 heavily pretreated patients with several types of advanced hematologic cancers and was well tolerated. Positive signs of anti-tumor efficacy were also observed; with one complete remission (28 months) and one partial responder (8 months).

Domatinostat strengthens the body's own anti-tumor immune response, influences the tumor and tumor microenvironment, making the tumor more visible to the immune system, and facilitates the infiltration of immune cells into the tumor.

These characteristics make domatinostat a potentially valuable combination partner for checkpoint inhibitors, particularly in patients with high unmet medical needs; such as patients who are refractory to checkpoint blockade or that show little response to treatment with checkpoint inhibitors such as microsatellite-stable gastrointestinal cancers.

Domatinostat in combination with checkpoint inhibitors

In order to evaluate domatinostat's combination potential, two Phase Ib/II clinical trials were initiated, in 2017 and 2019 respectively, with domatinostat in combination with a checkpoint inhibitor.

The Phase Ib/II SENSITIZE study is a dose escalation / dose expansion study of domatinostat in combination with the checkpoint inhibitor pembrolizumab – an anti-PD-1 antibody approved as a cancer immunotherapy against melanoma - in patients with advanced-stage melanoma who are refractory to anti-PD-1 antibody treatment.

The SENSITIZE Safety Review Committee – consisting of clinical and drug safety experts – positively evaluated the safety data from the three initial dose cohorts. Data from the SENSITIZE study was published at the European Society of Medical Oncology (ESMO) Congress in September 2019 from the first part of the study, where three patient cohorts were treated at three different dose levels of domatinostat in combination with pembrolizumab. At the time of data cut-off (15 July 2019, study still ongoing) a total of 23 patients were enrolled into the study:

- Domatinostat in combination with pembrolizumab was safe and well tolerated
  - no increase in frequency or intensity of immune-related adverse events (AEs) observed
- Signs of efficacy were observed, including one patient with a confirmed partial response and seven patients with stable disease (four confirmed)
  - indication of dose-dependency for domatinostat, with best results at the highest dose
- Preliminary biomarker analyses indicate a domatinostat-induced change in immunological tumor patterns

The Phase Ib/II EMERGE study, initiated in January 2019, is also a dose escalation / dose expansion study, conducted initially in up to 15 patients with microsatellite-stable gastrointestinal cancer. The study will evaluate domatinostat, in combination with the checkpoint inhibitor avelumab (an anti-PD-L1 antibody) as part of an investigator sponsored trial (IST) conducted by Professor David Cunningham at The Royal Marsden NHS Foundation Trust (London, UK). In July 2019, 4SC received a positive safety review for the safety of the combination of domatinostat + avelumab in the first dose cohort in EMERGE.

4SC expects to publish results from the dose escalation phase Ib of this trial in Q1 2020.

Domatinostat in Merkel cell carcinoma

In addition, it is also 4SC's intention - based on preclinical investigations and data from the SENSITIZE and EMERGE Phase Ib/II studies outlined above - to advance domatinostat into additional Phase II clinical studies in patients with Merkel cell carcinoma ("MCC").

MCC is a highly immunogenic, orphan type of non-melanoma skin cancer. In 2017, avelumab was approved in both the EU and U.S. for advanced metastatic MCC followed in December 2018 by pembrolizumab which was approved in the U.S. for the same indication. Although PD-1 and PD-L1 inhibitors are now standard of care in metastatic MCC, around half of all such patients still progress and currently lack any effective therapeutic options and suffer from high mortality.

To address the unmet medical need in advanced-stage MCC, 4SC intends to initially evaluate domatinostat in combination with checkpoint inhibition in up to 30 checkpoint naïve MCC patients (MERKLIN 1 study), as well as in up to 40 MCC patients progressed on treatment with checkpoint inhibitors (MERKLIN 2 study).

It is estimated that the MERKLIN 2 study will start in late 2019 and the MERKLIN 1 study mid 2020 and provide initial top-line data in the first half of 2021.

Domatinostat as neoadjuvant therapy in melanoma

In addition to the studies described above for MCC, it is also 4SC's intention to advance domatinostat into additional clinical studies in patients with earlier stage cutaneous melanoma as it is becoming clear that for cancer immunotherapy, the earlier treatment is given the higher the probability the patient will experience a durable response.

The term "neoadjuvant therapy" refers to an approach in which a form of therapy is given as a first step to shrink a tumor before the main treatment, which is usually surgery. Neoadjuvant therapy is already an approved clinical strategy in breast cancer and is rapidly gaining support in melanoma.

Alongside addressing later stage patients (as in the SENSITIZE study), 4SC believes that utilizing domatinostat in combination with immunotherapy as neoadjuvant therapy is a novel and strategically important positioning for the drug and as such, the Company entered into a collaboration with the Netherlands Cancer Institute (Stichting Het Nederlands Kanker Instituut (NKI) – Antoni van Leeuwenhoek Ziekenhuis) in Amsterdam to support a Phase II clinical study (DONIMI) in resectable stage III melanoma patients. The study will evaluate combining domatinostat and checkpoint blockade as neoadjuvant therapy in biomarker-selected sub-groups of such patients and is expected to start in Q4 2019. Top-line data from this neoadjuvant study could be available by late 2020.

OUT-LICENSED PROGRAMS

4SC continues to explore partnering opportunities in line with its strategy to monetize non-core assets.

In Q3 2019, 4SC received milestone payments from its cooperation partners Guangzhou Link Health Pharma Co., Ltd and Maruho Co., Ltd. in accordance with license and development agreements entered into in 2016, respectively 2017.

SIGNIFICANT CORPORATE EVENTS AFTER THE REPORTING PERIOD

In October 2019, the management board of 4SC resolved with the approval of the supervisory board to implement a capital increase to raise funds to continue to advance its drug development program for its second drug candidate domatinostat. In this context, an increase of 4SC's share capital shall be prepared, through the utilization of authorized capital from €35,325,216.00 by up to €10,647,553.00 to a maximum of up to €45,972,769.00, by issuing up to 10,647,553 new no-par value bearer shares, each with a notional par value of €1,00, against cash contribution. The existing shareholders of the Company, Santo Holding (Deutschland) GmbH and ATS Beteiligungsverwaltung GmbH irrevocably have committed to exercise the subscription rights held by them in full and to purchase - within the private placement - any and all Offer Shares not subscribed for by existing shareholders through the rights offering, or purchased by new investors within the private placement. 4SC will obtain total net proceeds of approximately €22 million from the offering.

DEVELOPMENT OF CASH FUNDS IN Q3 2019 AND FINANCIAL FORECAST

In June 2019, 4SC implemented a cash capital increase from authorized capital, resulting in net proceeds of circa €10.6 million. The transaction increased the share capital to €35,325,216 or 35,325,216 shares, up from €30,648,513 or 30,648,513 shares previously.

As of 30 September 2019, 4SC holds cash balance/ funds of €26,443 thousand as compared to €17,751 thousand as of 30 June 2019. The increase is a result of the capital increase in July as described above. The monthly use of cash from operations was below the range forecasted for 2019 amounting to €1,016 thousand on average in the first nine months of 2019 (9M 2018: €1,173 thousand).

The monthly use of cash from operations in the first nine months of 2019 was mainly driven by costs for the ongoing clinical studies RESMAIN and SENSITIZE.

Based on current financial and operating activities, the Management Board is expecting a lower average monthly cash burn rate from operations of between €1,300 thousand and €1,600 thousand for 2019 as compared to the earlier assumptions of €1,800 thousand to €2,000 thousand. The Management Board of 4SC confirms that the funds including proceeds from the capital increase as announced in October 2019, should be sufficient to finance 4SC into the second half of 2021.

OPPORTUNITIES AND RISKS

As 4SC's opportunities and risks have remained virtually unchanged, please see pages 18 to 25 of the Annual Report 2018 for a detailed description of the opportunities and risks arising from the Company's business activities as well as its IT-based risk management and controlling system.

The occurrence of any one of the risks described in the Annual Report – alone or in conjunction with each other – could have a negative impact on the results of operations, financial position and net assets of 4SC.

FINANCIAL CALENDAR 2020

Annual Report 2019	25 March 2020
Q1 Announcement 2020	21 April 2020
Annual General Meeting 2020	8 May 2020
Half-Year Report 2020	11 August 2020
Q3 Announcement 2020	20 October 2020

PUBLISHING INFORMATION

PUBLICATION DATE

17 October 2019

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4SC ON THE INTERNET

More information about 4SC, its products and development programs, is available on the Company's website, www.4sc.com, as well as the following information:

- Previous reports on 4SC's progress and outlook
- Audio recordings of conference calls
- Presentations
- General investor information

CORPORATE COMMUNICATIONS & INVESTOR RELATIONS

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